Enabling Pharma 4.0 with Structured Data Frameworks for Knowledge and Quality Risk Management

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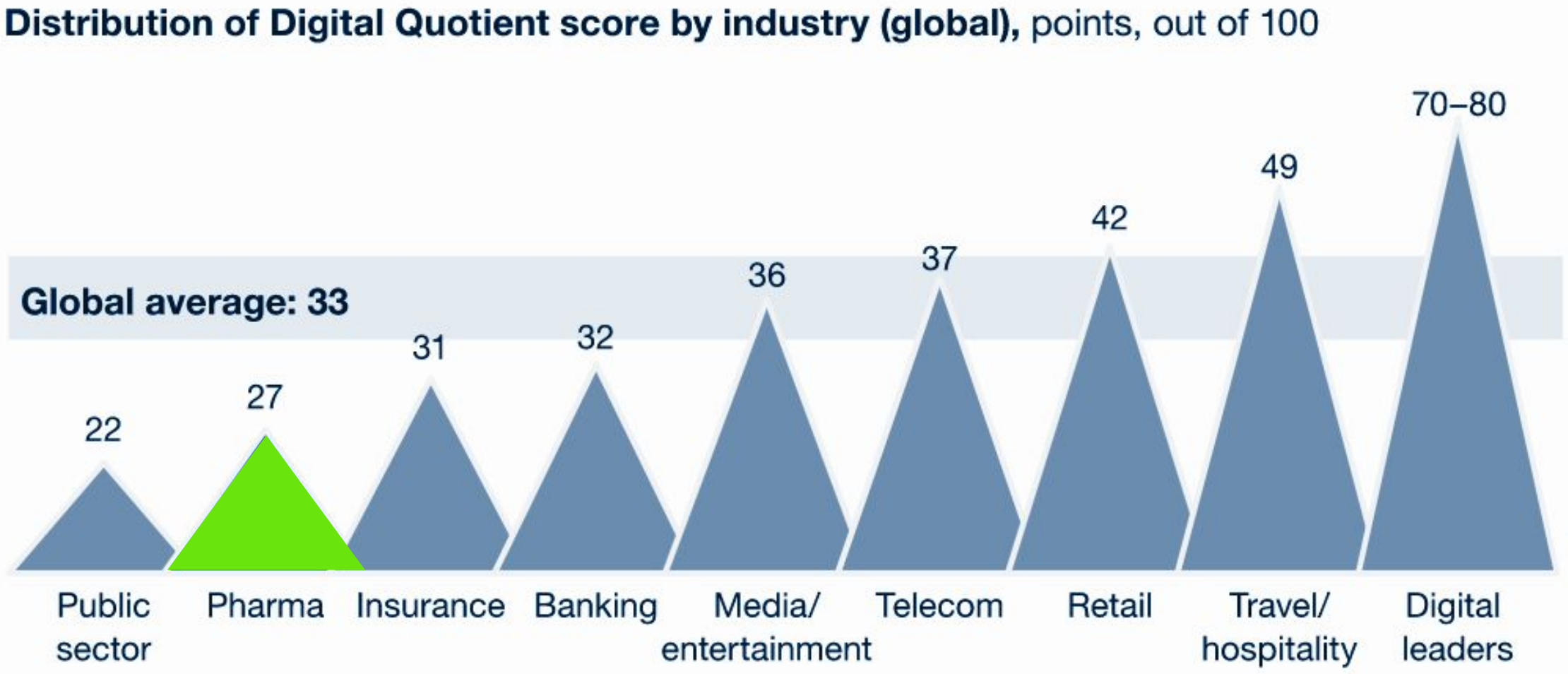
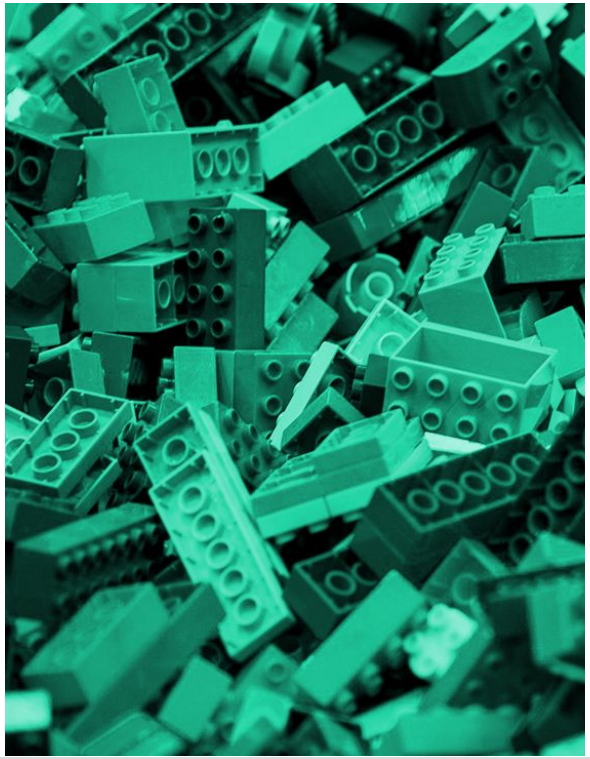
Pharma Struggling With Digital Maturity

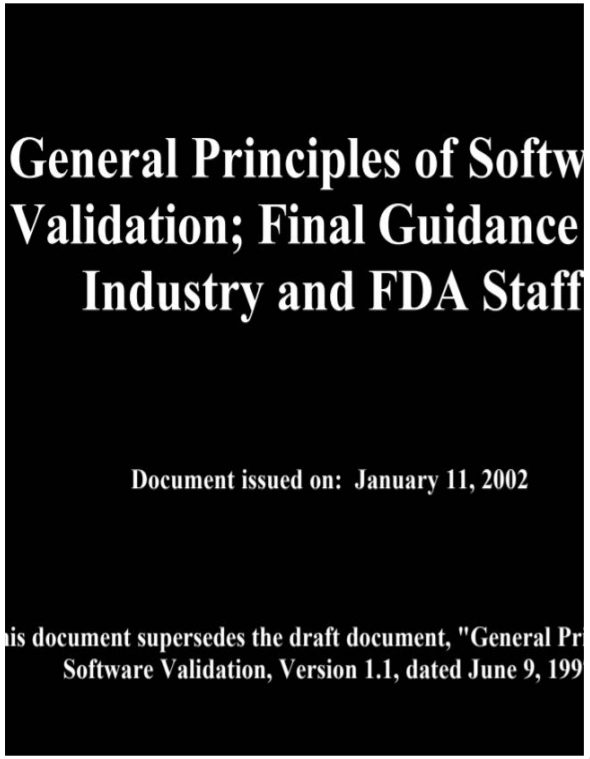


Source: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/closing-the-digital-gap-in-pharma

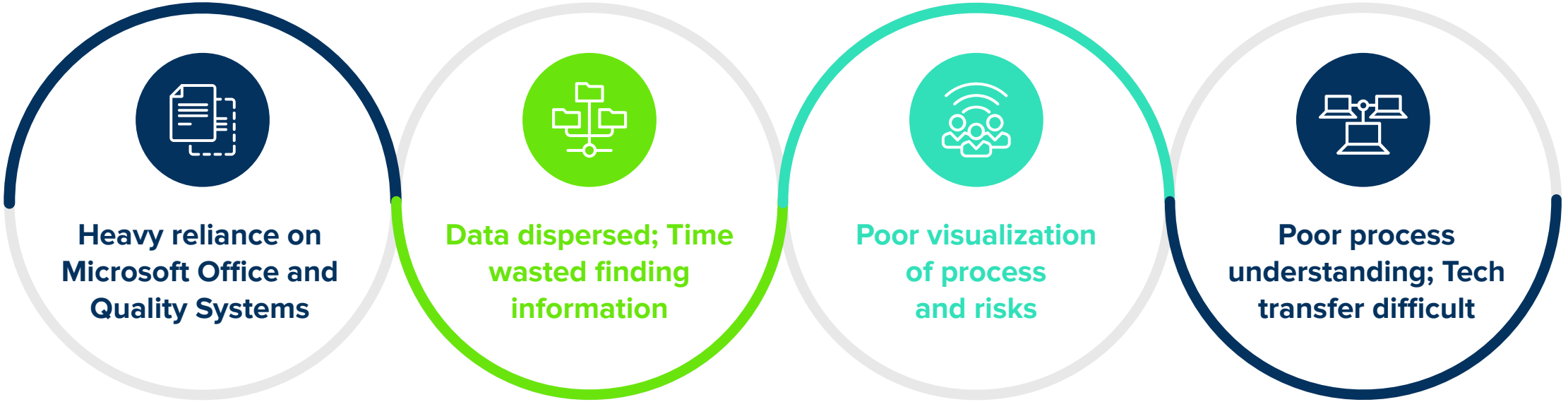
Barriers to Digital Maturity

Heavily Document-Focused	Lack of Structure & Integration	Software Validation Requirements	Hard to Change Behavior





Knowledge Management Is Challenging

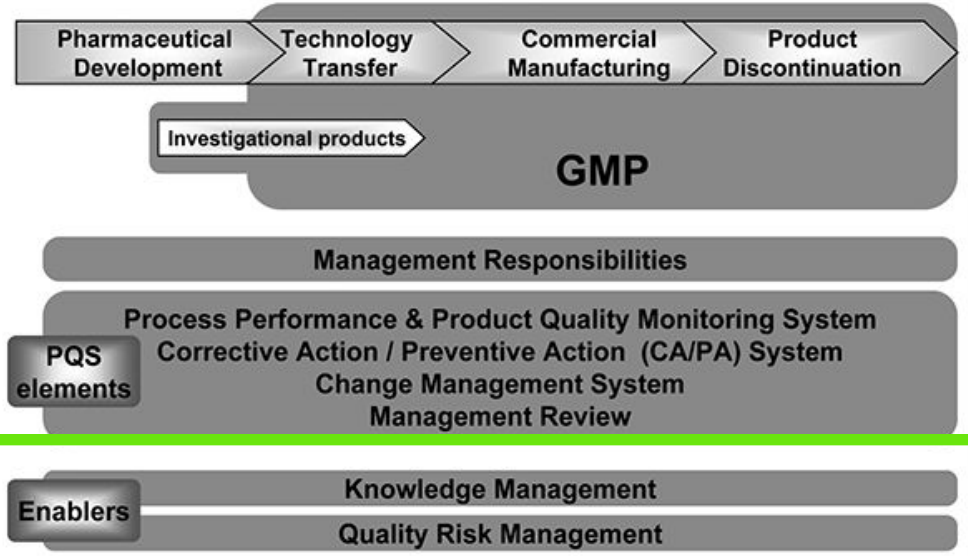


QUALITY-BY-DOCUMENTATION	INFORMATION SILOS	CHALLENGING TO MANAGE COMPLEXITY	UNDER DEVELOPED PRODUCTS

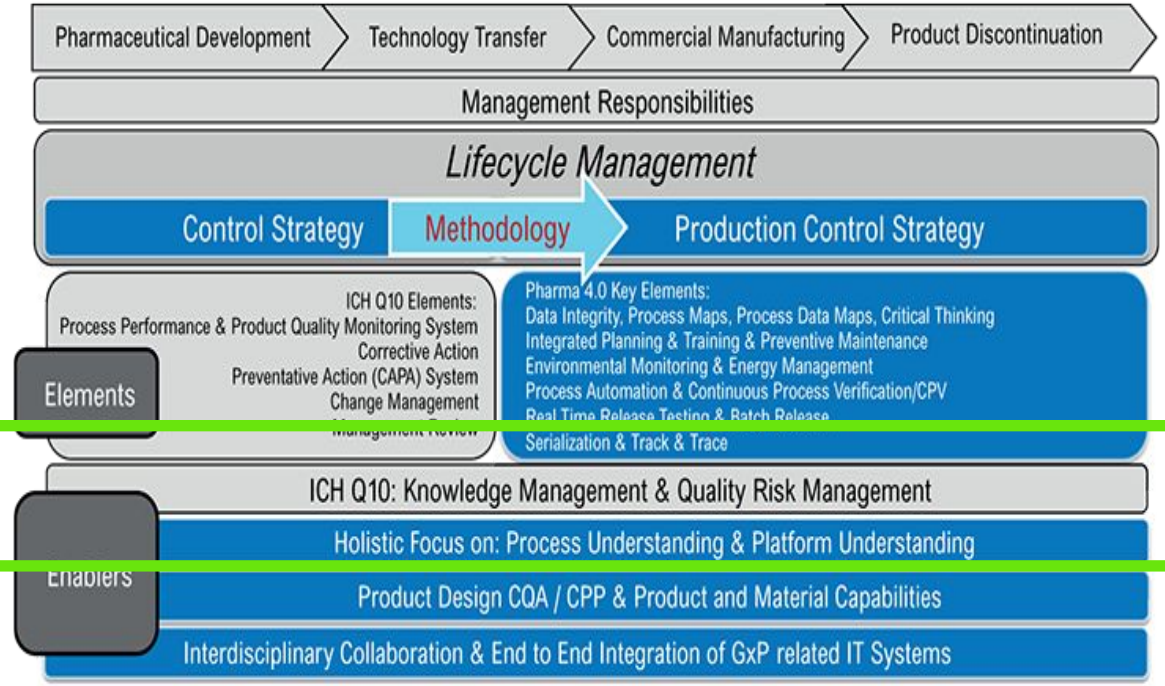
AFFECTS PRODUCT QUALITY AND DATA INTEGRITY

Pharma 4.0[1] to the Rescue?

ICH Q10 System



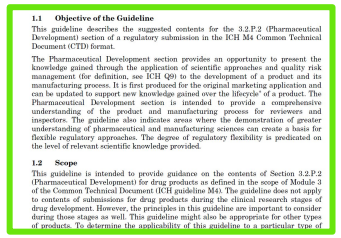
Pharma 4.0



1. Dr. Christoph Herwig, Christian Wölbeling, and Thomas Zimmer, PhD, A HOLISTIC APPROACH TO PRODUCTION CONTROL FROM INDUSTRY 4.0 TO PHARMA 4.0, Pharmaceutical Engineering, May 2017.

Fundamental Problem Is… Unstructured Data

eQMS



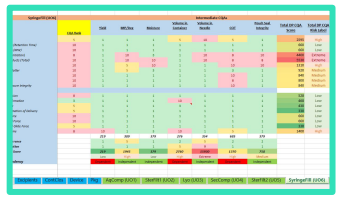
1.1 Objective of the Guideline

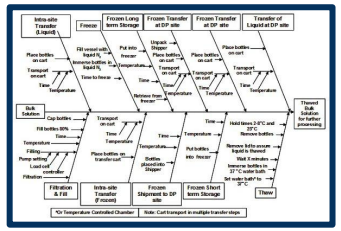
This guideline describes the suggested contents for the 3.2.P.2 (Pharmaceutical Development) section of a regulatory submission in the ICH M4 Common Technical Document (CTD) format.

The Pharmaceutical Development section provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management (for definition, see ICH Q9) to the development of a product and its manufacturing process. It is first produced for the original marketing application and can be updated to support new knowledge gained over the lifecycle* of a product. The Pharmaceutical Development section is intended to provide a comprehensive understanding of the product and manufacturing process for reviewers and inspectors. The guideline also indicates areas where the demonstration of greater understanding of pharmaceutical and manufacturing sciences can create a basis for flexible regulatory approaches. The degree of regulatory flexibility is predicated on the level of relevant scientific knowledge provided.

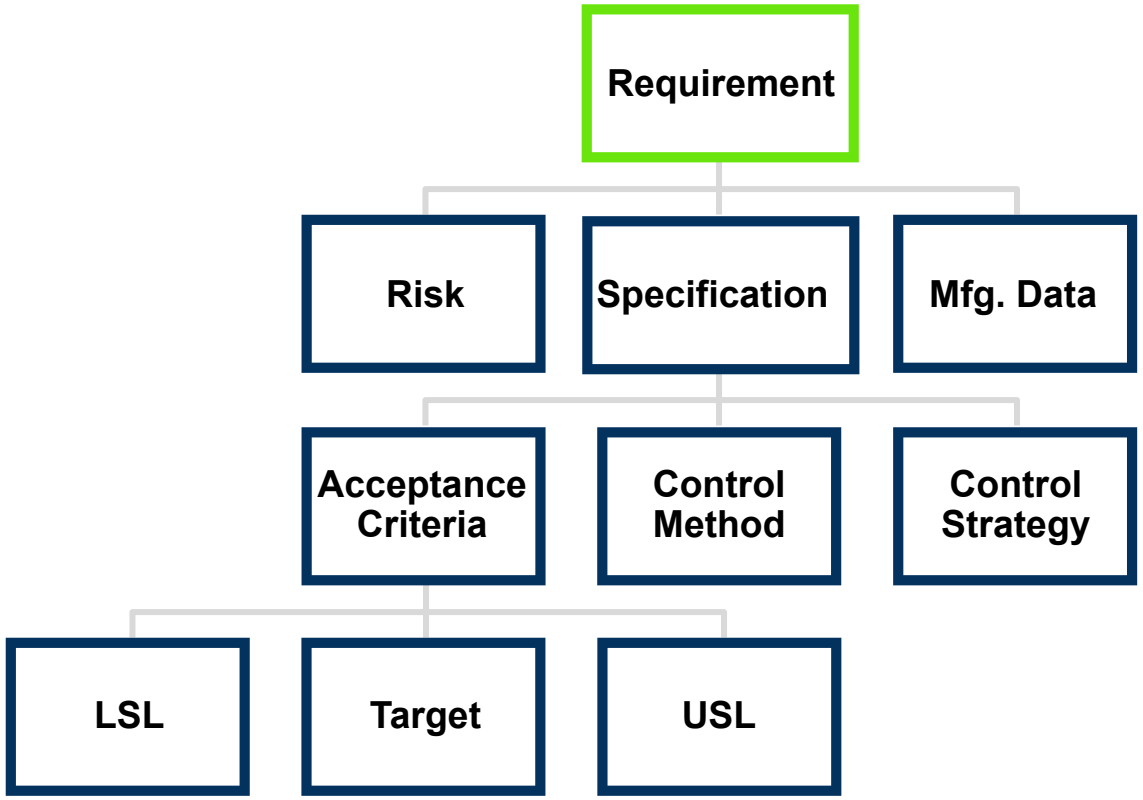
1.2 Scope

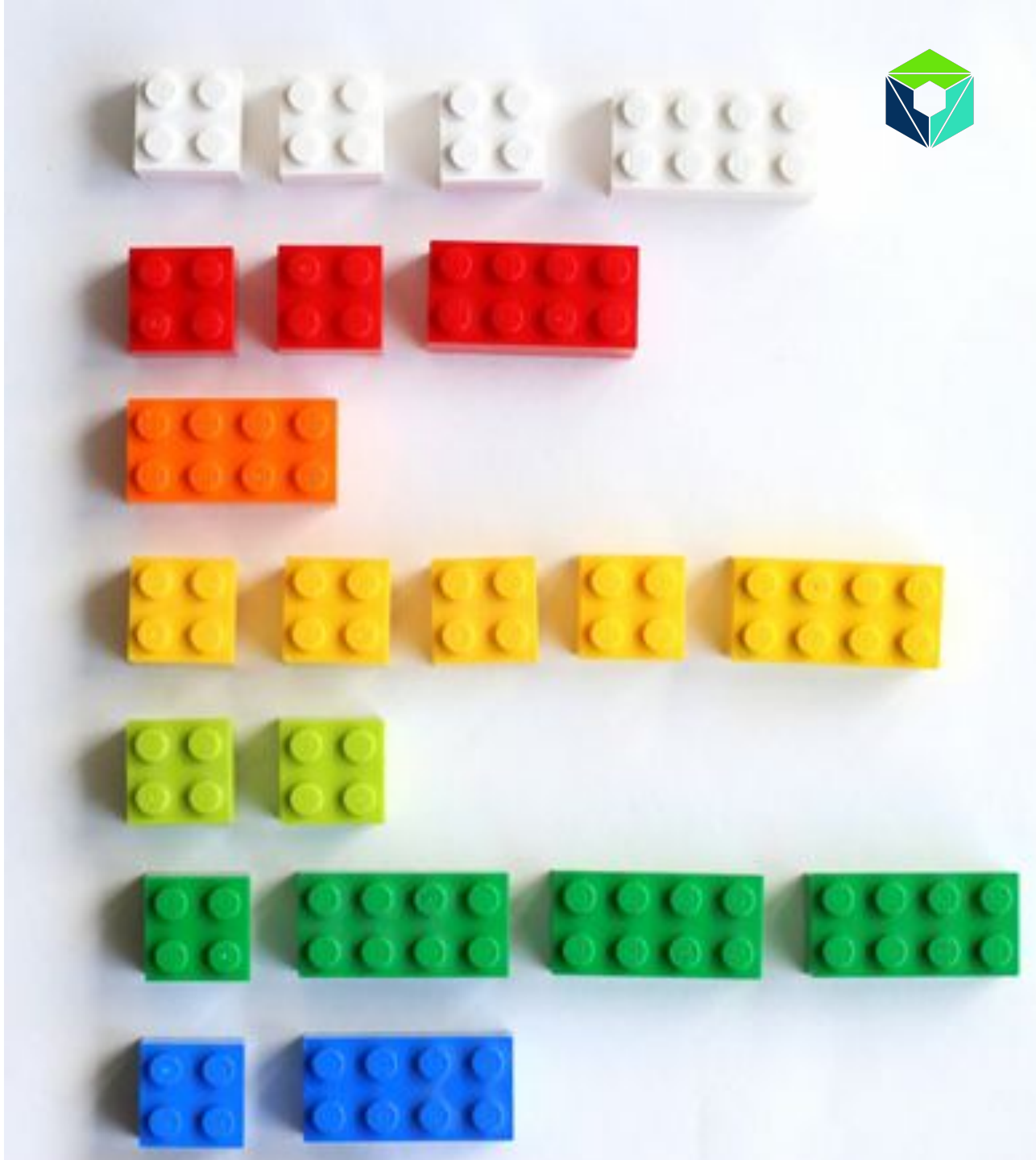
This guideline is intended to provide guidance on the contents of Section 3.2.P.2 (Pharmaceutical Development) for drug products as defined in the scope of Module 3 of the Common Technical Document (ICH guideline M4). The guideline does not apply to contents of submissions for drug products during the clinical research stages of drug development. However, the principles in this guideline are important to consider during those stages as well. This guideline might also be appropriate for other types of products. To determine the applicability of this guideline to a particular type of



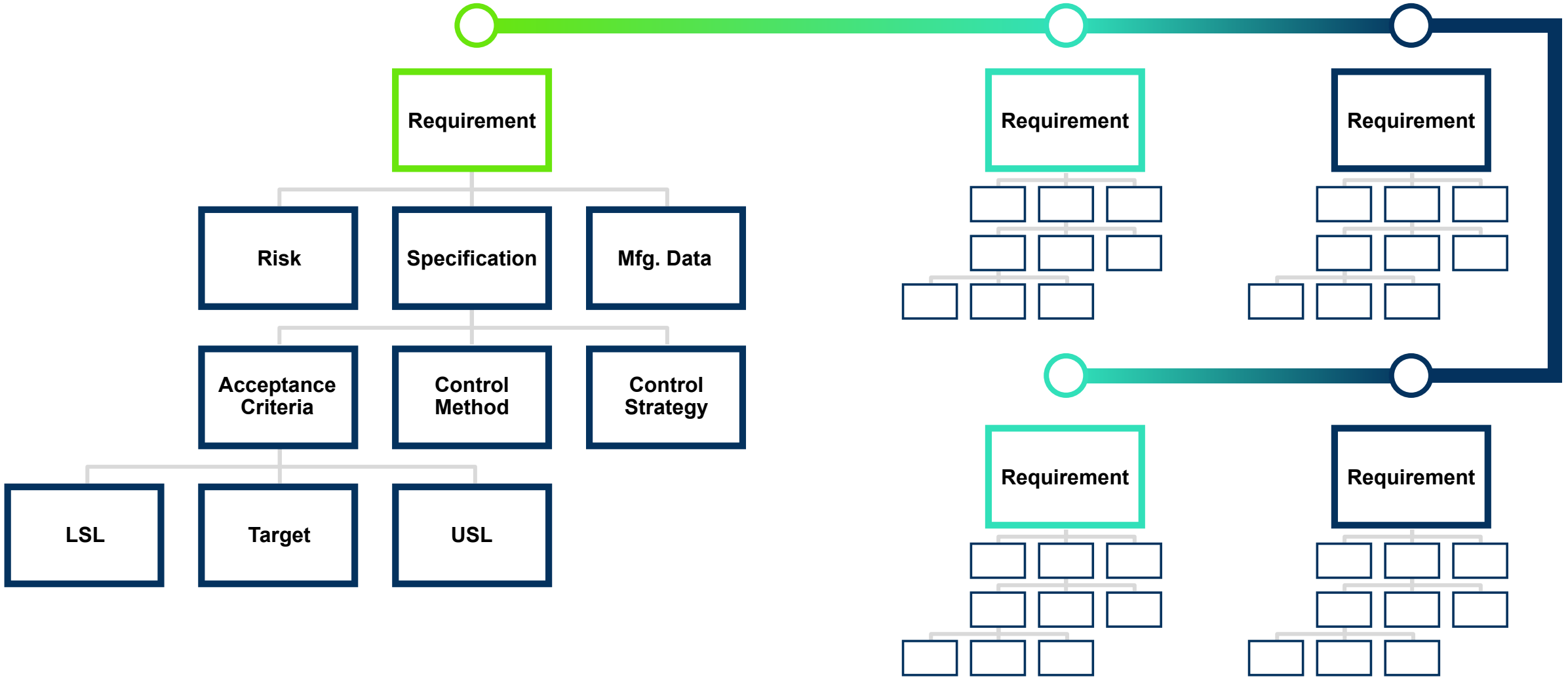


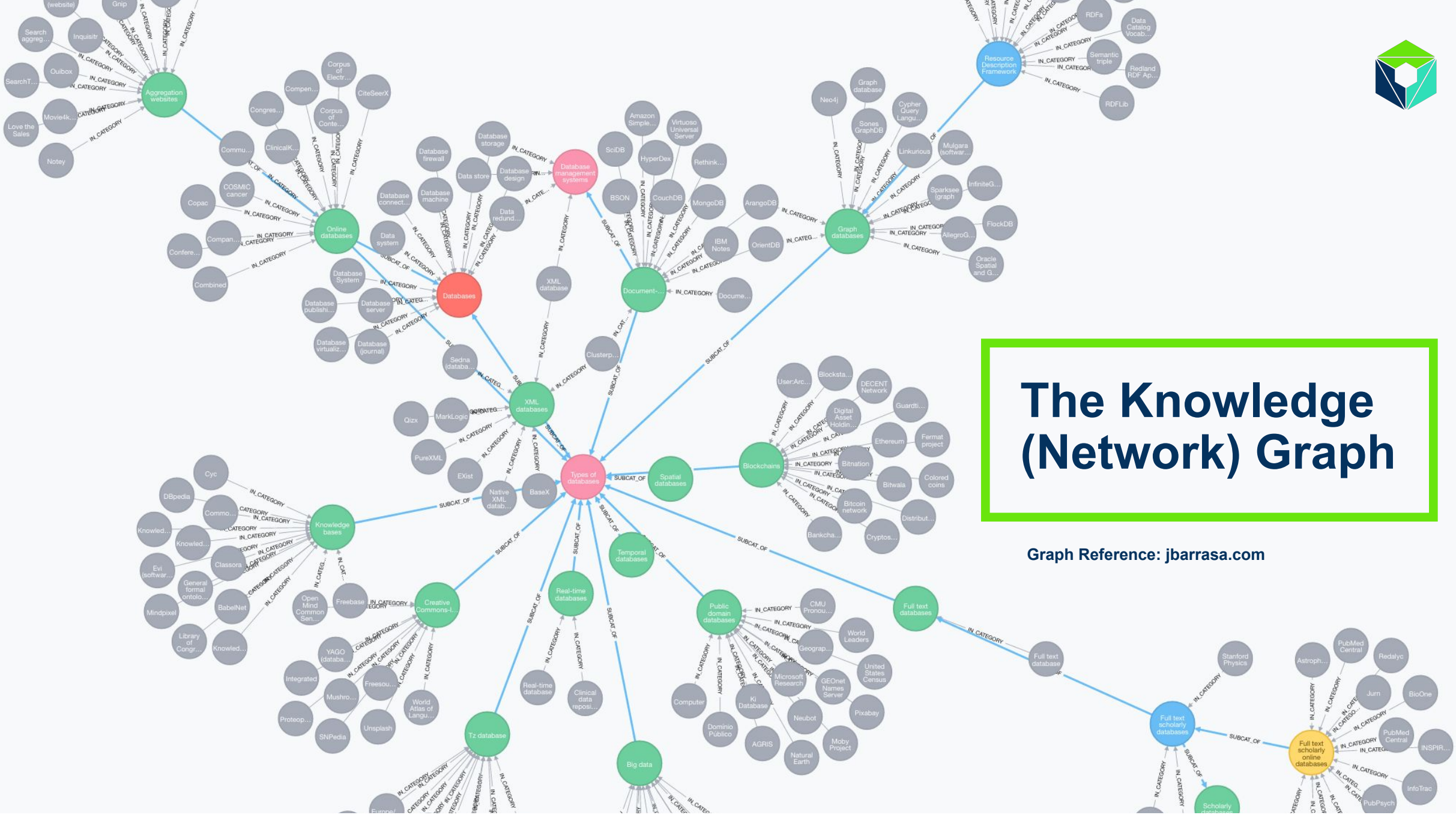
How Should We Structure Data?





Granular Structure Enables Linking!

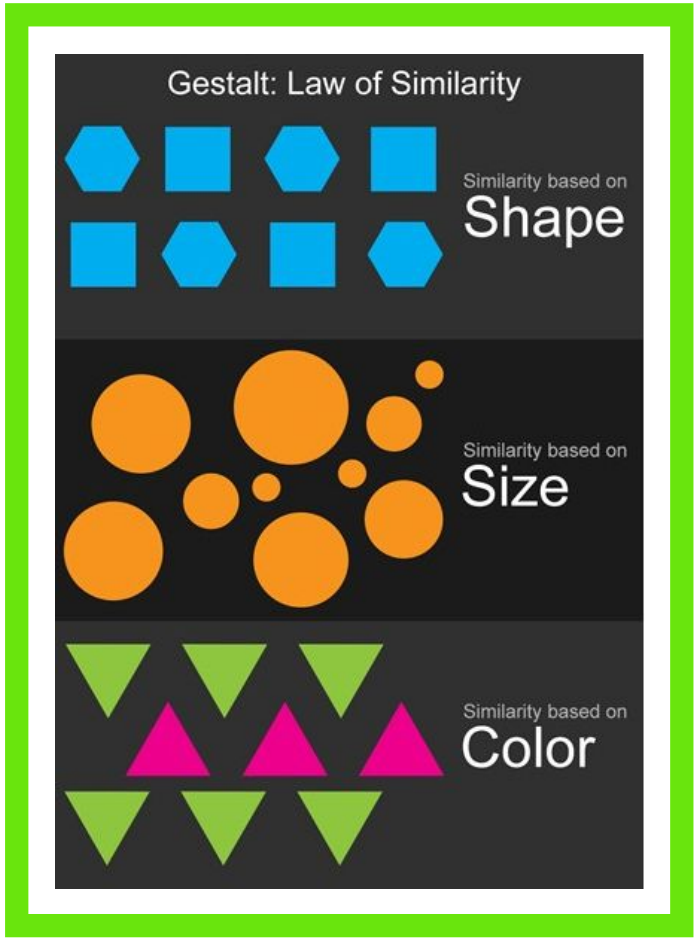


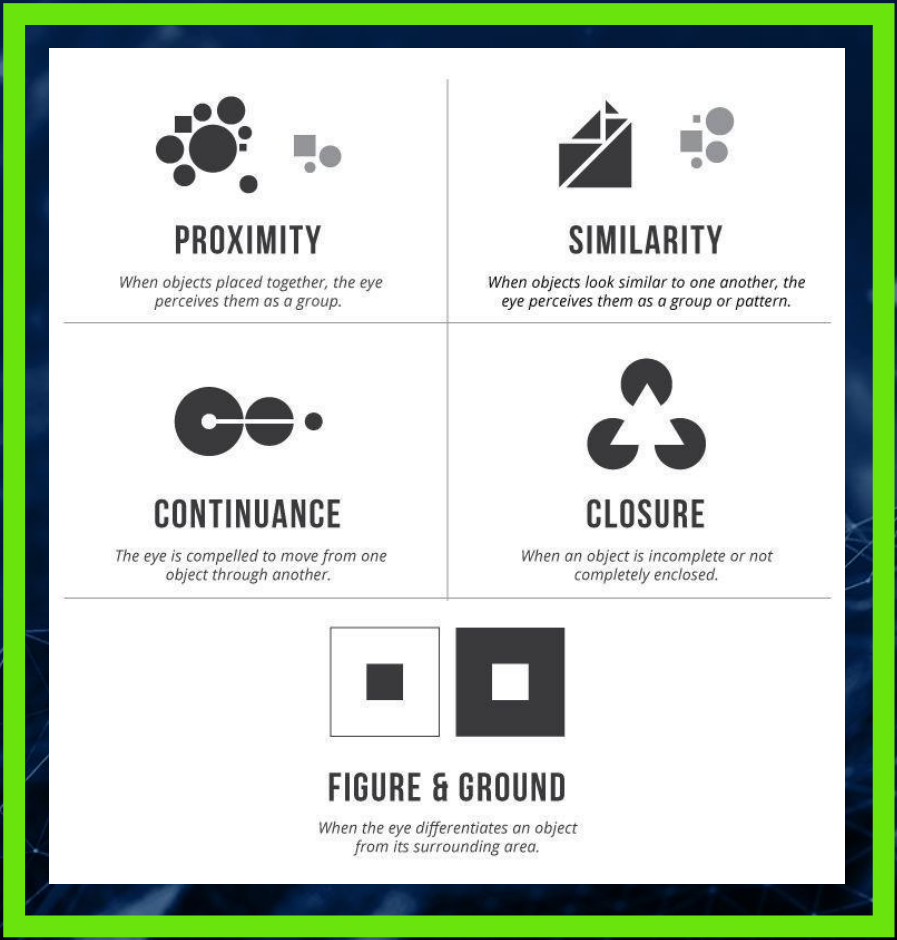


The Knowledge (Network) Graph

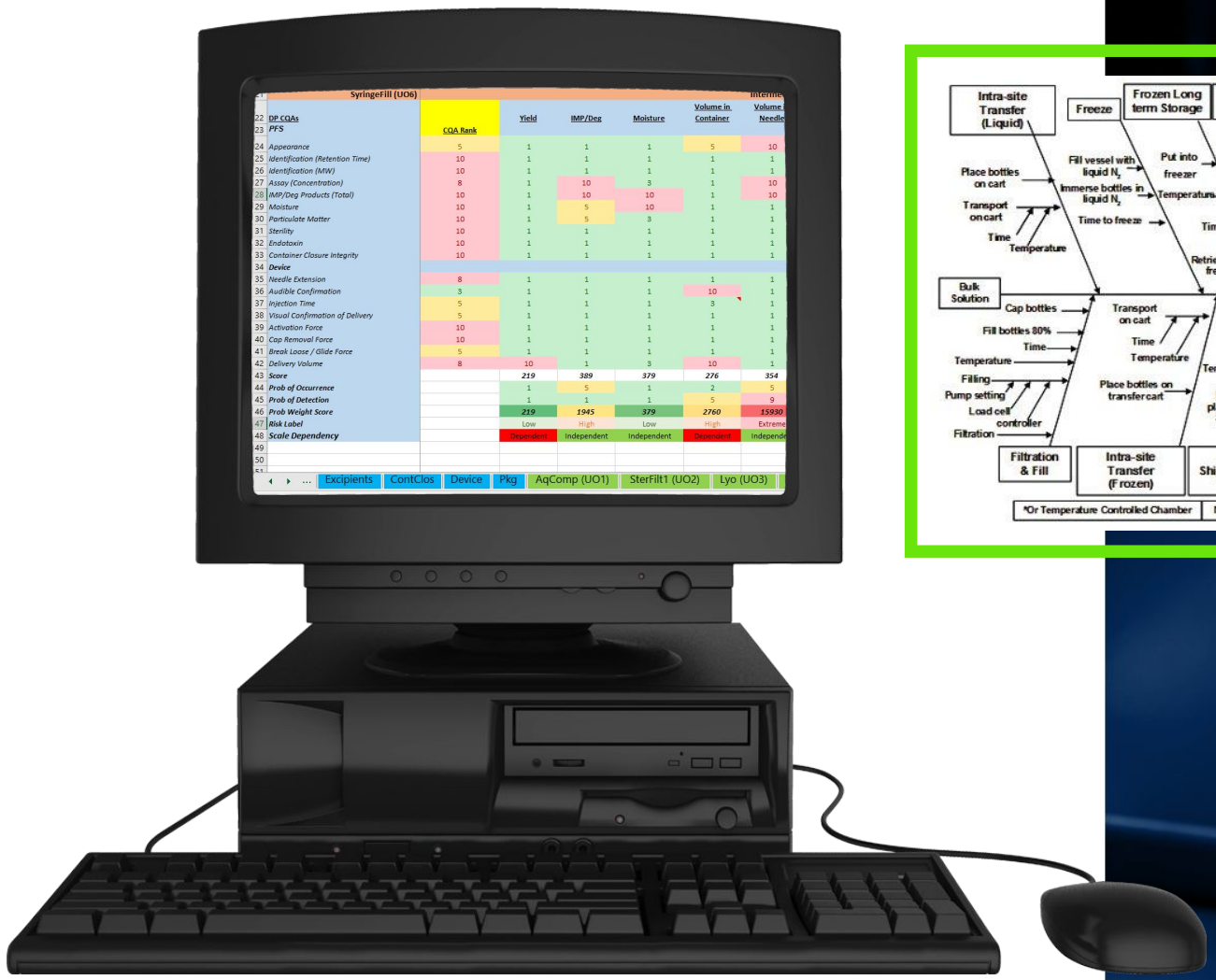
Graph Reference: jbarrasa.com

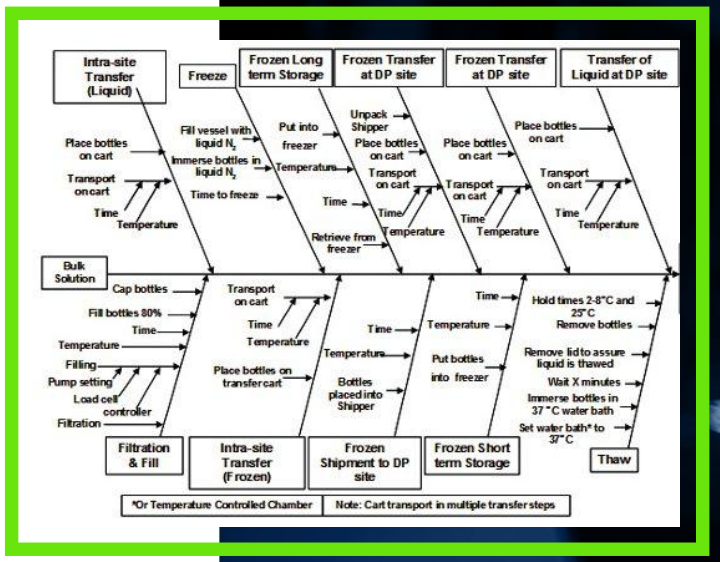
Theory of Visual Perception





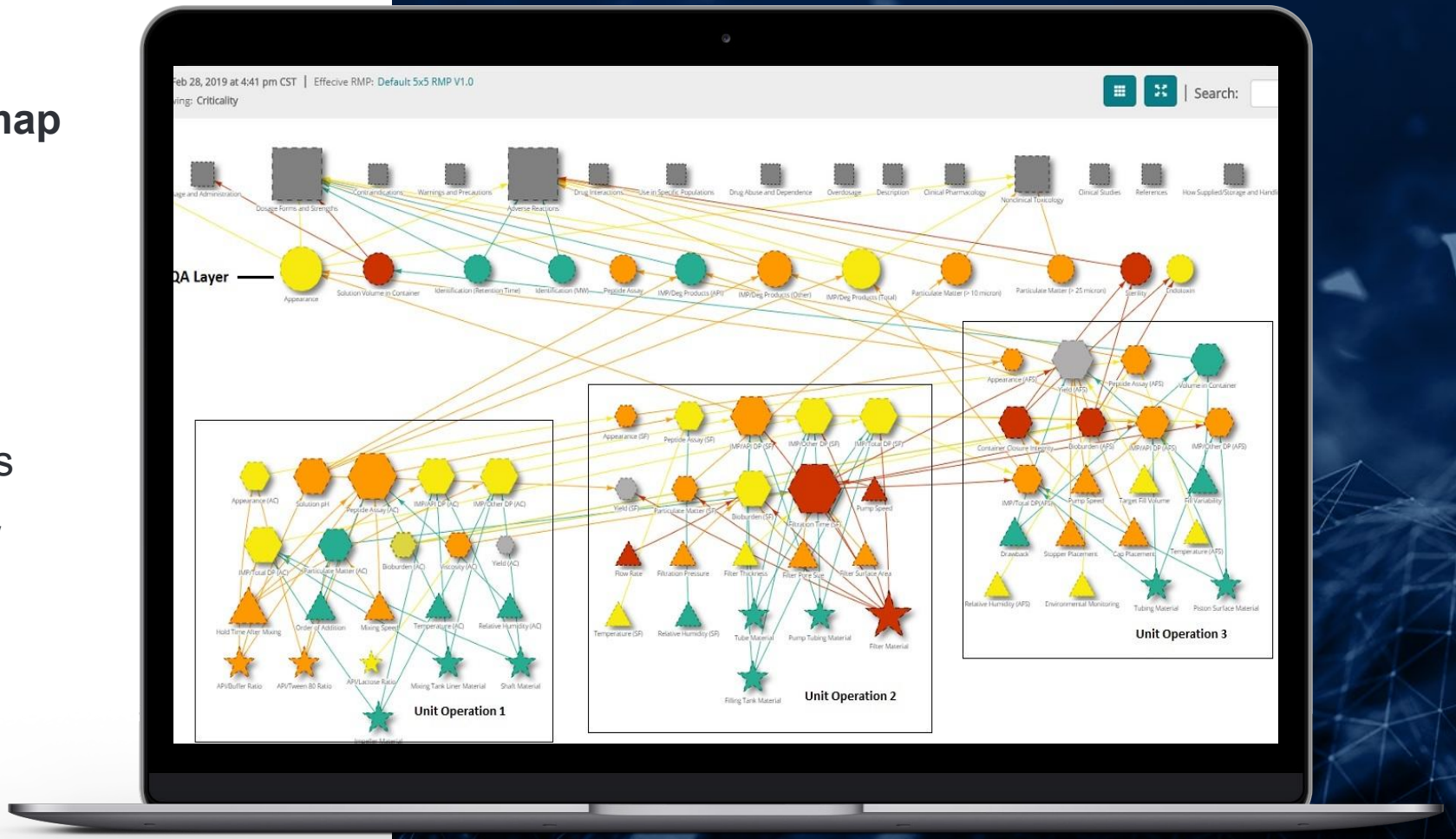
Spreadsheets & Fishbones



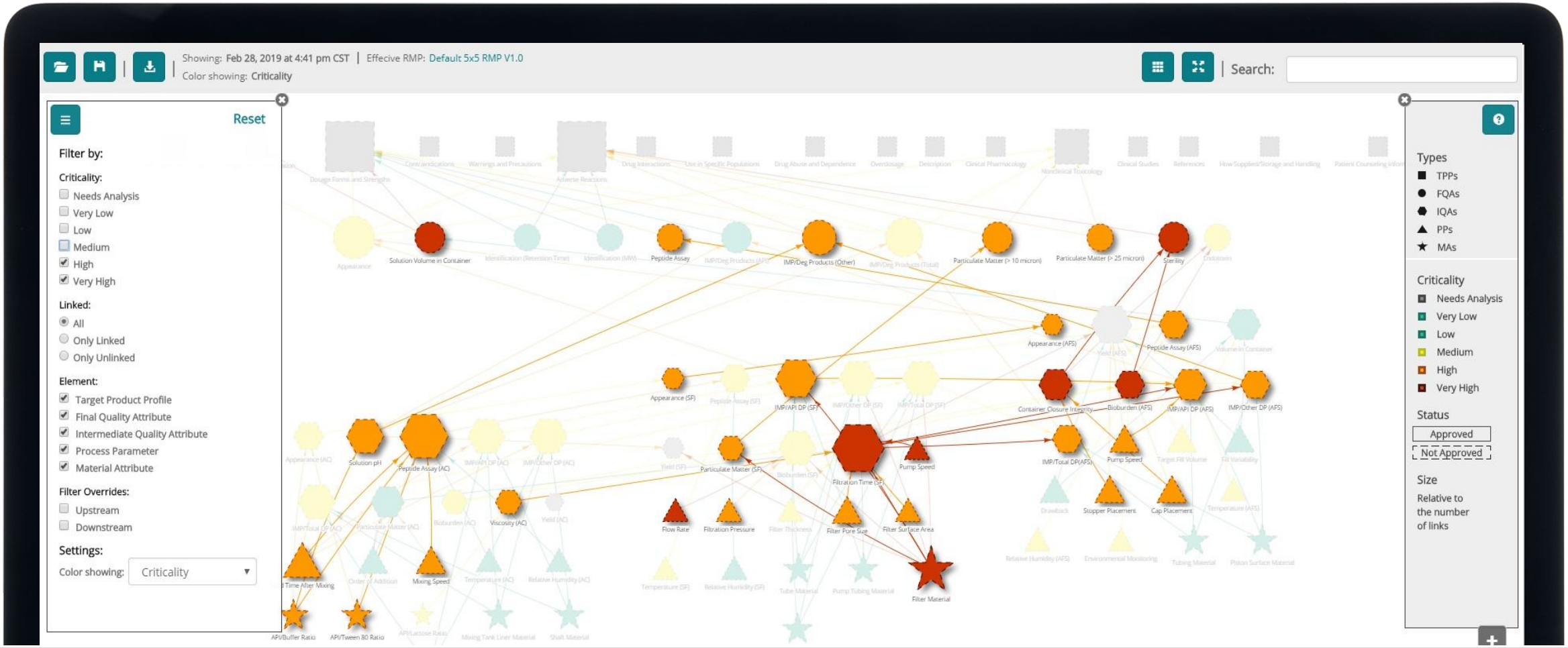


Represent Process as a Network Graph

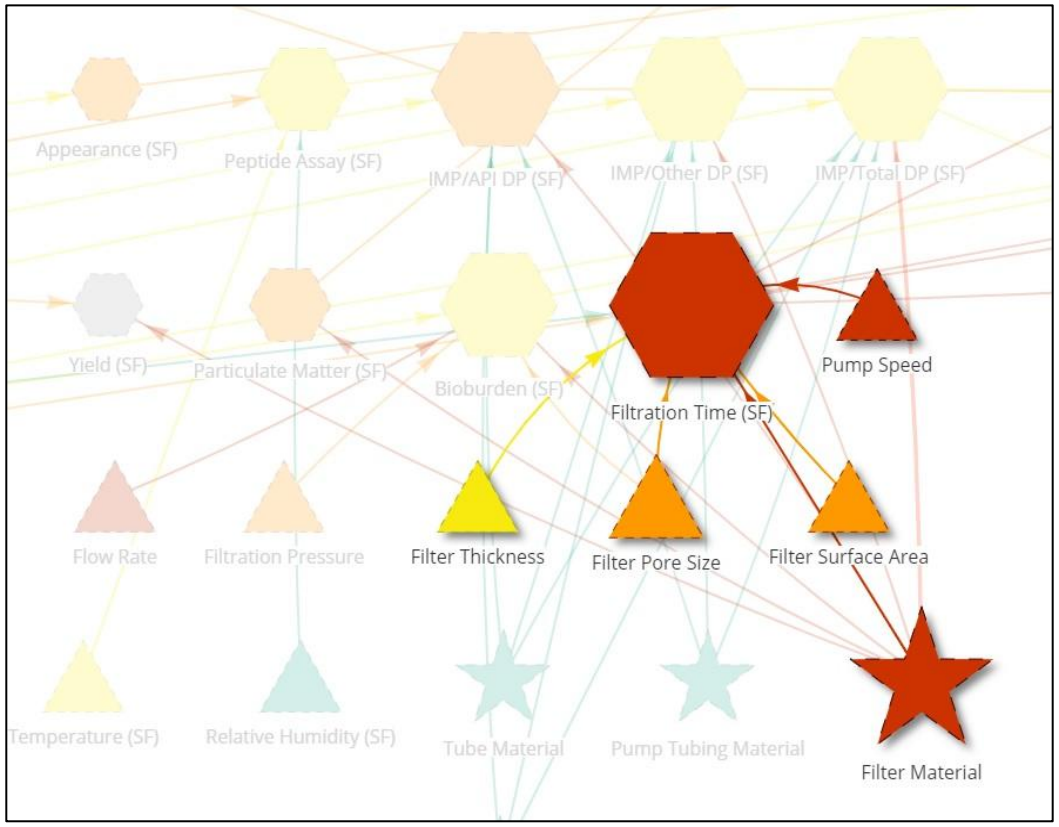
- **View 7 dimensions in one map**
- **Hierarchy:** Requirements (Patient, Product, Process)
- **Shape:** QA, MA, PP, etc
- **Color:** Risk
- **Size:** Proportional to # of links
- **Links:** Cause & Effect (follow process flow)
- **Clusters:** Unit Operation
- **Shape Border:** Status



Easily Filter Dimensions of Interest



Visual Cause and Effect (Part 1)

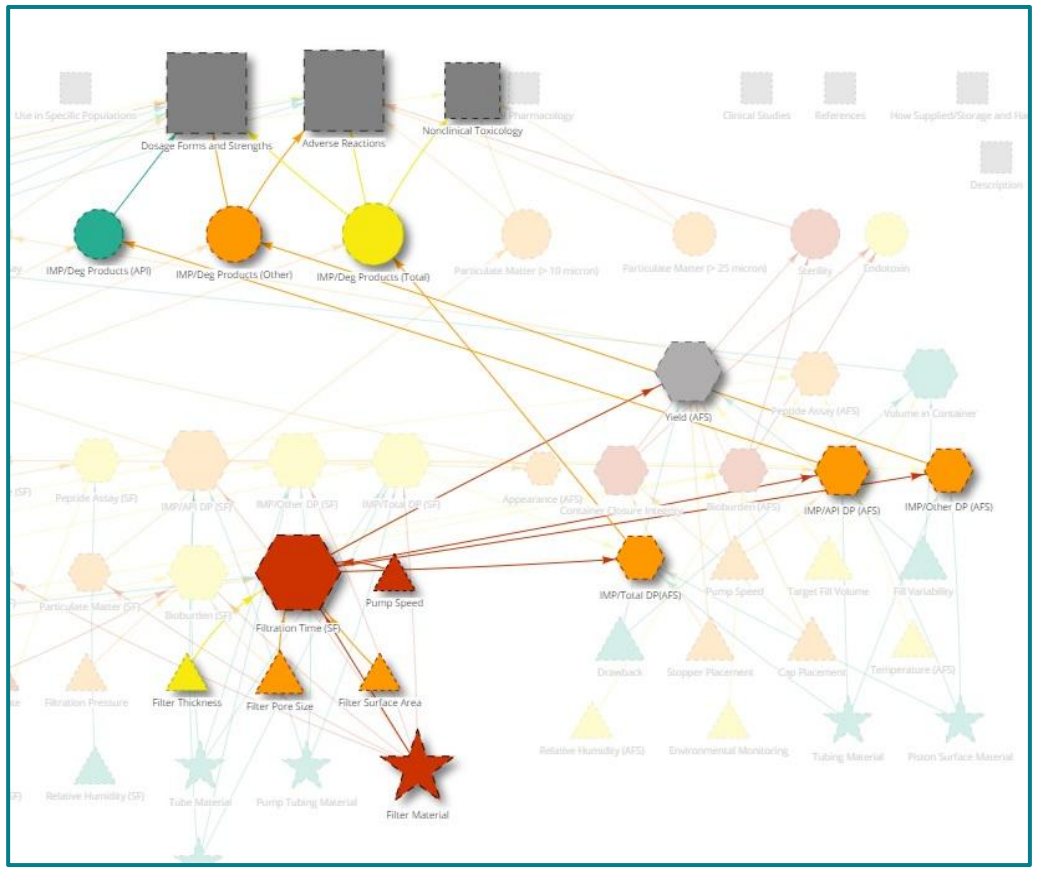


Visualize relationship of inputs to an output in the process (traceability)

Suggests possible DOE configuration for further characterization

Provides scientific rationale for root-cause investigation

Visual Cause and Effect (Part 2)

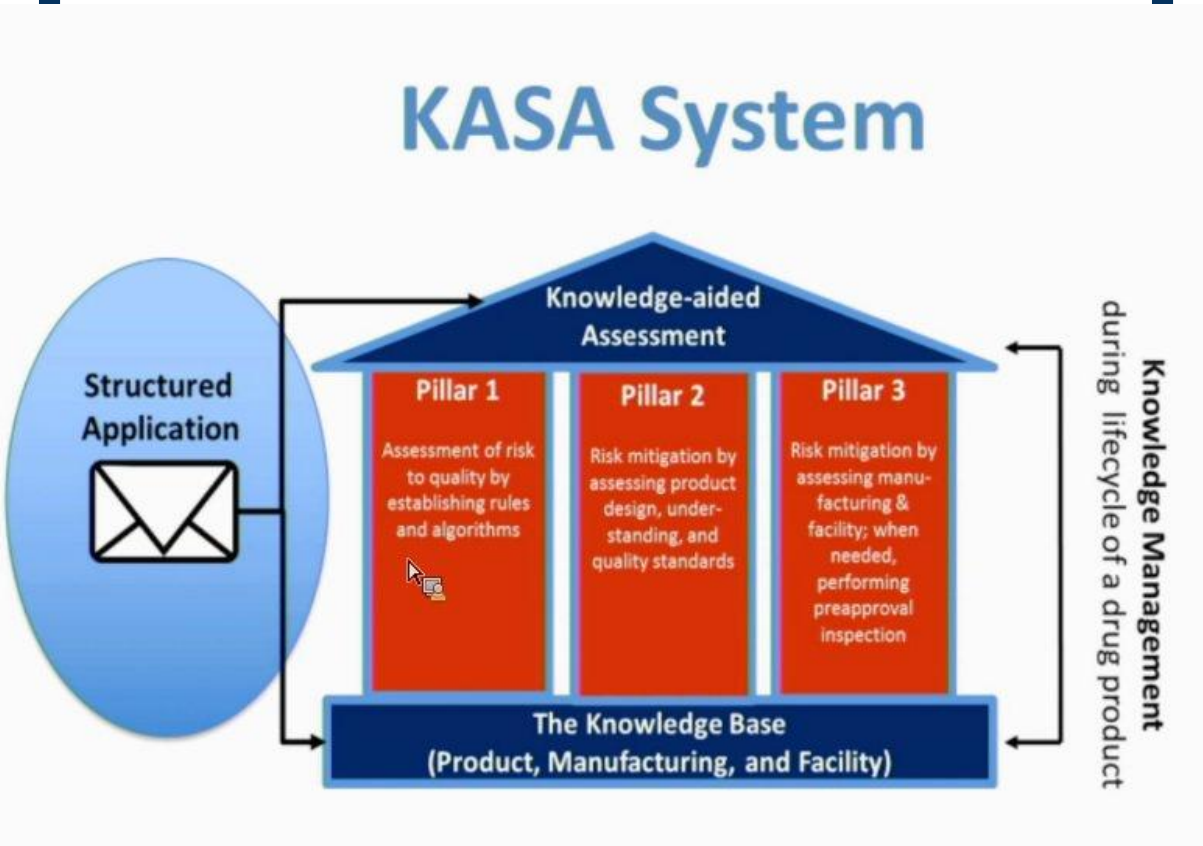


See the effects of an intermediate output on the downstream process

Cause and effect mapping follows process flow

Useful for impact assessment of process change (ICH Q12)

KASA Initiative (FDA)

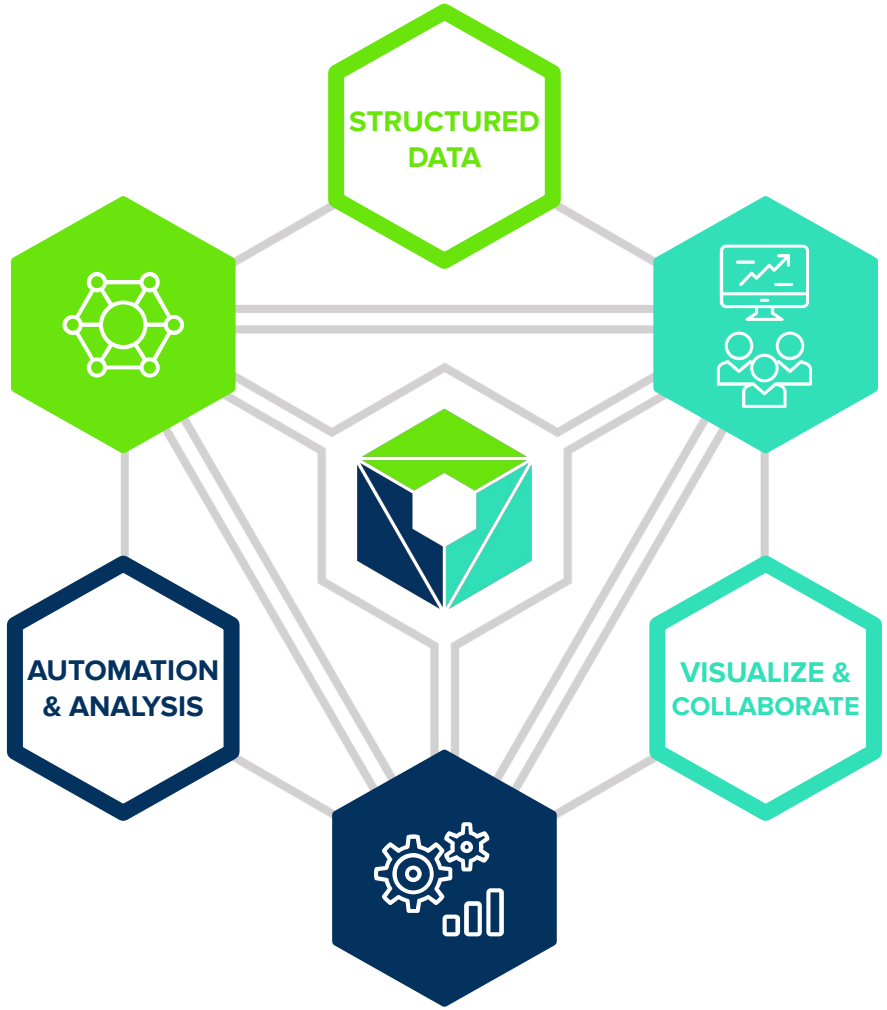


- Internal evaluation of structured system to facilitate assessment
- Structured systems can facilitate consistency and efficiency when sharing information
- Collaboration needed between industry & regulatory agencies to realize full benefits

Automate Compliance

Structured Framework Allows:	ICH Q8	ICH Q8 (Annex)	ICH Q9	ICH Q10	ICH Q11	ICH Q12
Requirements Definition						
Requirements Traceability						
Integrated Risk Assessment						
Linking Testing & Requirements						
Visualization of Cause & Effect						
Data & Testing Linked to Requirements						
Management of Established Conditions						
Post-Approval Change Mgmt.						

Improving Digital Maturity for Pharma 4.0



- Less Time Wasted Searching
- Stop “Paper on Glass”
- Automate Manual Tasks
- Use Your Valuable Data
- Robust Change Management
- Holistic QbD & Data Integrity
- Improve Product Quality

Thank You!

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